DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JAN 24 2000

7982 '00 FEB -8 P1:59

Mr. David Kropp
Acting Director, Regulatory and Consumer Affairs
Pharmavite Corporation
15451 San Fernando Mission Boulevard
P.O. Box 9606
Mission Hills, California 91346-9606

Dear Mr. Kropp:

This is in response to your letter to the Food and Drug Administration (FDA) dated January 5, 2000 pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Pharmavite Corporation is making the following statements, among others, for various products containing Red Rice Yeast as a single ingredient or in combination with other ingredients:

> "Clinically shown to help promote healthy cholesterol levels"
> "Red Rice Yeast has been clinically shown to help promote healthy cholesterol levels naturally by inhibiting the production of LDL cholesterols."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to prevent, treat, cure, or mitigate diseases, namely hypercholesterolemia. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B) and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

In your letter, you state that the products that are the subject of the above claims contain the ingredient red yeast rice.

975-0163

LET-330

We wish to advise you of the current status of products that contain red yeast rice. FDA announced its administrative decision on May 20, 1998 that a product named "Cholestin[1]", manufactured by Pharmanex, Inc., which was promoted as a dietary supplement intended to affect cholesterol levels, is not a dietary supplement, but is instead an unapproved drug under the FD&C Act. This decision meant that Cholestin could not be legally sold in the United States.

On February 16, 1999, the United States District Court for the District of Utah "held unlawful and set aside" the FDA's administrative finding of May 20, 1998. FDA has appealed the District Court's decision to the United States Court of Appeals for the 10th Circuit. The future regulatory status of all red yeast rice products will depend, in part, on the decision of the courts on the merits of the Cholestin matter. At this time, FDA believes that products containing red yeast rice or *Monascus purpureus* that contain lovastatin are unapproved new drugs that are in violation of the FD&C Act.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret, Jr.
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

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[1]Cholestin consists of the yeast *Monascus purpureus* when fermented on premium rice powder. The fermentation of the rice with this yeast, under certain conditions, produces a product that contains lovastatin, the active ingredient in the prescription cholesterol-lowering drug Mevacor.

cc:
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (file)
HFS-450 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605
GCF-1 (Dorsey, Barnett, Nickerson, Parker)
HFV-228 (SBenz)
f/t:HFS-456:rjm:1/21/00:docname:pharvite.adv:disc44

PHARMAVITE

January 4, 2000

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

(1) Name and address of manufacturer:
Pharmavite Corporation, PO Box 9606, Mission Hills, CA 91346

(2) Text of the statement(s):

Clinically shown to help promote healthy cholesterol levels.

Red Rice Yeast has been clinically shown to help promote healthy cholesterol levels naturally by inhibiting the production of LDL cholesterols.

Red Rice Yeast has been a part of the Asian diet for centuries and should be used as part of a cholesterol regimen which includes a healthy diet and regular exercise.

(3) Name of the dietary ingredient if not provided in the text of the statement:
see above

(4) Name of the dietary supplement:
products containing Red Rice Yeast as a single ingredient or in combination with other ingredients

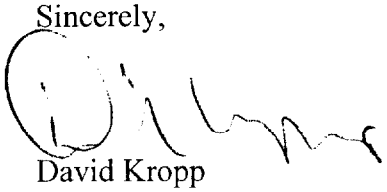
The above statement(s) may be used in one or more of the following brands of products: Nature Made, Sunny Maid, Nature's Resource, AAFES, AARP, Osco, Sav-On, Valu Wise, Bartell Drug, CVS, Duane Reade, Walgreens, Longs, Spring Valley, Brite Life, Family Pharmacy, GNP, Valu-Rite.

Pharmavite Corporation • 15451 San Fernando Mission Boulevard • P.O. Box 9606 • Mission Hills, CA 91346-9606 • 818/837-3633 213/875-0948

PHARMAVITE

We certify the information in this notice is complete and accurate, and we have substantiation that the above statement(s) is truthful and not misleading.

Sincerely,



David Kropp
Acting Director, Regulatory and Consumer Affairs